

OCT 1 8 2000

K002444

**SAFETY AND EFFECTIVENESS SUMMARY
FOR
MODEL 1010 DOSIMETRY ELECTROMETER/
MODEL 206 ELECTROMETER**

The Sun Nuclear Model 1010/Model 206 Dosimetry Electrometer is an effective but simple Dosimetry Electrometer. It operates on 6 "D" Cell batteries which makes it very safe for the user. The Model 1010/Model 206 has all of the features to serve the basic needs of the physicist who is measuring radiation with an ionization chamber. The University of Wisconsin – Madison Department of Medical Physics has furnished Sun Nuclear with a report which demonstrates the linearity and accuracy of the unit.

Sun Nuclear has deemed the device safe and effective for its intended uses as long as it is operated in accordance with all of the accompanying labeling and instructions. Sun Nuclear believes that responsible design and quality assurance practices were followed during the development and manufacture of the Model 1010/Model 206 Dosimetry Electrometer.

SAFETY FEATURES LIST FOR MODEL 1010/MODEL 206

<u>FEATURE</u>	<u>PURPOSE</u>
1. Battery Operated	Meets stringent electrical requirements for safety
2. Zero adjust Control	Controls leakage to < 0.0001pA
3. MOSFET	Keeps electrometer ready for use at all times
4. Bias Check	Provides measurement of thimble bias and polarity

510(k) Premarket Notification Summary

Submitter: Sun Nuclear Corporation
425-A Pineda Court
Melbourne, FL 32940
Phone (407) 259-6862
Fax (407) 259-7979

Contact: Noel Downey

Date: March 16, 1998

Trade Name: Model 1010 Dosimetry Electrometer/Model 206 Dosimetry
Electrometer

Common Name: Electrometer

Classification Name: Accessory to Accelerator, Linear, Medical

Product Code: 90IYE

Substantial Equivalence: Victoreen Model 530 Precision Electrometer/Dosimeter
#K931927 and Keithley Instruments Advanced Therapy Dosimeter Model 350470
#K942083.

Description and Use:

The Model 1010/Model 206 Dosimetry Electrometer is a reference grade instrument used to measure ionizing radiation in medical diagnostic and therapeutic procedures. This unit maintains the simplicity of a classic electrometer while utilizing contemporary design and state-of-the-art electronics.

The Model 1010/Model 206 has a broad range of operation and can accommodate any size ion chamber utilizing most types of connectors. This electrometer is very versatile due to its modular design. The module is removable and can be exchanged with any number of modules.

Similarities/Differences with predicate devices:

Similarities between the Sun Nuclear Model 1010/Model 206 Electrometer and the other two marketed devices (Victoreen Model 530 and Keithley Model 35040) are:

- 4 & ½ Digit display precision
- Leakage current less than 10 fA
- High input impedance electrometer circuit
- Built in chamber bias supply
- Bipolar measurement capability (+ or – current)
- Triax input connectors with floating electrometer circuit

The main difference between Sun Nuclear Unit and the other two marketed devices is that there is no microprocessor or software in the Model 1010/Model 206. The 1010/206 also differs from the 530 and 35040 in the following ways:

- Input connector and electrometer feedback element are contained in a module which can be exchanged for another by a screw lock mechanism. The module defines the input style, measurement range, units, and calibration.
- Coax input in addition to triax input (useful for diode measurements and some ion chambers terminated coaxially)
- No rechargeable power supply batteries, 1010/206 uses standard D cells which last more than 1000 hours
- No RS-232 Computer connection
- Manual zero compensation
- Only one chamber factor for conversion to dosimetry units included with the input connector module, but each chamber can be connected to the electrometer with it's specific module.
- Only four internal Bias selections from the front panel, but these satisfy the basic needs of electron beam measurement with bias reversal and recombination studies at 50% normal bias measurements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2000

Thomas L. Powers
President
Sun Nuclear Corporation
425-A Pineda Court
Melbourne, FL 32940

Re: K002444
Model 1010 Dosimetry Electrometer/
Model 206 Dosimetry Electrometer
Dated: July 25, 2000
Received: August 9, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Powers:

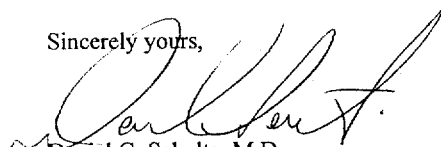
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002444

Device Name: Sun Nuclear Corporation Model 1010 Electrometer

Indications For Use:

The Model 1010 Dosimetry Electrometer is intended for measurement of ionization current in radiation dosimetry applications.

The electrometer is intended for basic applications in medical physics such as:

- Research
- Machine calibration
- Daily constancy tests
- Chamber recombination analysis
- Photon and electron dosimetry
- Mammography and diagnostic x ray QA measurements

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

David A. [Signature] OR
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002444

Over-The-Counter Use _____

(Optional Format 1-2-96)